GT GreenbergTraurig

Lori G. Cohen
Tel. 678.553.2385
Fax 678.553.2386
cohenl@gtlaw.com

March 18, 2022

VIA ECF

Honorable Madeline Cox Arleo
United States District Court for the District of New Jersey
M. L. King, Jr. Federal Building
& U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07102

Re: ***In re: Metformin Marketing and Sales Practice Litigation***
Civil Action No. 2:20-cv-02324 (MCA) (MAH)

Dear Judge Arleo:

We represent Defendants Actavis Pharma, Inc., Actavis LLC,[1] Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries Ltd. (collectively the "Teva Defendants"). We are writing this letter on behalf of all Defendants who have appeared.[2]

As you are aware, currently pending before Your Honor are Motions to Dismiss filed by Defendants (ECF No. 132 for Manufacturing Defendants and ECF No. 133 for the Pharmacy Defendants). We are writing to bring to Your Honor's attention a relevant decision recently decided which directly relates to the pending Motions to Dismiss before Your Honor. A copy of this decision is enclosed as Exhibit 1 to this letter.

On February 16, 2022, the Honorable Denise L. Cote of the Southern District of New York entered the enclosed order in the matter of *Harris v. Pfizer Inc.* granting defendant Pfizer Inc.'s Motion to Dismiss the plaintiffs' putative class actions, which alleged economic loss claims based on the presence of N-nitroso-varenicline (a nitrosamine) in Pfizer's Chantix—a prescription drug used to help consumers stop smoking. The *Harris* plaintiffs alleged several causes of action identical to Plaintiffs' Amended Consolidated Economic Loss Class Action Complaint in the instant litigation, including: (1) fraud, (2) negligent misrepresentation, (3) breach of express warranty, (4) breach of the implied warranty of merchantability, (5) violation of New Jersey's Consumer Fraud Act, (6) violation of New York General Business Law §§ 349, 350, and (7) unjust enrichment. Defendants submit Judge Cote's ruling on Pfizer's Motion to Dismiss these causes of

[1] Improperly named as "Actavis, LLC."
[2] Defendants Teva Pharmaceutical Industries Ltd., Emcure Pharmaceuticals Ltd., Aurobindo Pharma Ltd., and Alkem Laboratories Ltd., have only specially appeared to argue the Court lacks personal jurisdiction over them. (*See* ECF No. 132-1).

action as it may assist this Court in its consideration of similar issues raised in Defendants' pending Motions to Dismiss.

In particular, Defendants direct the Court's attention to the following relevant aspects of Judge Cote's Order:

- **Fraud**: "The plaintiffs allege that Pfizer made two misrepresentations: first, that the product they purchased was 'Chantix', as approved by the FDA; and second, that the product contained only the active ingredient varenicline. The plaintiffs argue that these representations were false or misleading because the medication was contaminated by N-nitroso-varenicline. But neither the product label nor the medication guide state that varenicline is the only biologically active ingredient in Chantix. And presence of a contaminant does not render the brand name on the label false – contaminated Chantix is still Chantix." (Exhibit 1, at 10-11) (emphasis in original). The Court held that the plaintiffs' Amended Complaint "alleges no facts to suggest that the Chantix they purchased differs in any way from the drug approved by the FDA, much less that it differs so much as to no longer be Chantix." (*Id.* at 11). The Court further held that while the plaintiffs' Amended Complaint "alleges that nitrosamine had been detected in other drugs by 2018, and that one of Pfizer's distributors was warned in October of 2020 that its supply of varenicline was at risk of contamination as well[,] these allegations . . . at most only show that Pfizer may have known that its medication was at risk of contamination by late 2020. They do not show that Pfizer knew or believed that Chantix was actually contaminated, particularly when the plaintiffs purchased Chantix in 2019 and the spring of 2020." (*Id.*) (emphasis in original).

- **Negligent Misrepresentation**: "Because the plaintiffs claim only economic harm, rather than personal injury, the economic loss doctrine bars their negligent misrepresentation claim." (*Id.* at 17). The Court further held that "the alleged misrepresentation here—that the drug the plaintiffs purchased was Chantix with the active ingredient varenicline—is not a separate statement that induced the plaintiffs to enter into a contract with Pfizer; it is the statement that the plaintiffs allege actually constituted the contract that Pfizer breached. And second, the [First Amended Complaint] again fails to plausibly allege that Pfizer made any misrepresentation." (*Id.*).

- **Breach of Express Warranty**: "The [First Amended Complaint] does not plausibly allege that Pfizer breached any express warranty. The plaintiffs argue that nitrosamine contamination breached Pfizer's promise that the medication sold was Chantix, with the active ingredient varenicline. But again, the presence of a nitrosamine does not mean that the medication they received was not Chantix, or that it did not contain the active ingredient varenicline." (*Id.* at 21).

- **Breach of Implied Warranty of Merchantability**: "The plaintiffs argue that the medication was unmerchantable because it contained N-nitrosovarenicline in excess of the legal limit. But this does not establish that the Chantix was unfit for its ordinary purpose.

On the contrary, in announcing the recall, the FDA stated that there was 'no immediate risk' to patients taking Chantix, and urged patients to continue taking the drug even after the recall. FDA Updates and Press Announcements on Nitrosamine in Varenicline (Chantix), FDA (Sept. 17, 2021), https://www.fda.gov/drugs/drug-safety-andavailability/fda-updates-and-press-announcementsnitrosamine-varenicline-chantix." (*Id.* at 23-24).

- **Violation of New Jersey's Consumer Fraud Act**: "Harris' NJCFA claim fails for largely the same reasons as her fraud claim. The FAC does not plausibly allege that Pfizer made any misrepresentation, as it pleads no facts to show that the brand name or active ingredient listed on the product label were inaccurate. And to the extent that the NJCFA claim is premised on Pfizer's failure to disclose the presence of N-nitrosovarenicline, the plaintiffs have not plausibly alleged that Pfizer knew that its medication was contaminated by a nitrosamine when the plaintiffs purchased it, or that Pfizer intended to defraud them." (*Id.* at 14-15).

- **Violation of New York General Business Law §§ 349, 350**: "A plaintiff does not have a claim under the [NY General Business Law] just because she comes away from an advertisement with an incorrect impression. That impression must be reasonably traceable to a misleading statement from the defendant." (*Id.* at 19). Plaintiff failed to identify any misleading statements by Pfizer. (*Id.* at 20).

- **Unjust Enrichment**: "The only allegations in the [First Amended Complaint] specific to the unjust enrichment claim state that Pfizer accepted and kept the plaintiffs' money obtained from selling Chantix. . . . But the plaintiffs do not explain why their unjust enrichment claim is distinct from their other claims, or distinct from a conventional tort or contract action. Accordingly, the unjust enrichment claim is dismissed." (*Id.* at 25).

Thank you for your consideration of this supplemental authority. Should you have any questions regarding the above, please feel free to contact us.

Respectfully Submitted,

/s/Lori G. Cohen
Lori G. Cohen, Esq.

Attorney for Defendants Actavis Pharma, Inc., Actavis LLC, and Teva Pharmaceuticals USA, Inc.

Enclosures – Exhibit 1 *Harris v. Pfizer Inc.* Order Granting Motion to Dismiss

cc: All Counsel of Record (*via ECF*)